Screening Agreement for Submitting Products to the Division of Acquired Immunodeficiency Syndrome (AIDS), National Institute of Allergy and Infectious Diseases, hereafter referred to as the DIVISION,

by

_____, hereafter referred to as the SUPPLIER.

1. The SUPPLIER may supply products, patented or unpatented, to the DIVISION which may proceed to screen and test for possible treatment for AIDS and associated opportunistic infections including tuberculosis. These products are to be used for screening and testing as anti-viral, anti-bacterial, anti-fungal, anti-parasitic, immunomodulating, and biological modifying agents with potential for the treatment of AIDS and associated infections, and for no other purpose.

   Using protocols evaluated and approved mutually by the DIVISION and the SUPPLIER, the products will be screened by one or more of the DIVISION's contract testing laboratories, or in any other testing laboratories which may from time to time be added to the DIVISION's portfolio but in any event will not be placed in the laboratories of any company in the pharmaceutical or chemical industries without the SUPPLIER's written permission.

2. In order to facilitate records keeping and handling of confidential materials, the DIVISION utilizes the following procedures:

   a. The SUPPLIER shall forward to the DIVISION the products to be tested together with data sheets in duplicate for each product, giving pertinent available data as to chemical constitution, solubility, toxicity, previous biological efficacy and any precautions which need to be followed in handling, storing, and shipping.

   b. It is clearly understood that no data about the products and the results of the testing will be kept in files open to the public either by the DIVISION, the testing laboratories, or the data processing activities. Only those employees directly engaged in the operation of the DIVISION will have access to the files of information regarding source and nature of confidential materials and results of testing, except as required pursuant to the Freedom of Information Act, 5 U.S.C.552.

   c. Whenever possible the SUPPLIER will be given the choice of the DIVISION's contract testing laboratories, although at present there is no preference; and it is understood that the DIVISION reserves the right to send the SUPPLIER's products to another screening contractor if the need arises. It is furthermore understood that the contracts between the DIVISION and the testing laboratories will contain provisions to safe guard the SUPPLIER's rights under this Agreement.

   d. Because the DIVISION's screening effort will be accomplished in collaboration with the DIVISION's scientific staff and academic collaborators, as well as the SUPPLIER's own staff, the DIVISION will work in concert to assure rapid ongoing communications of

screening data to the SUPPLIER, and the SUPPLIER will in turn use its best efforts to keep the DIVISION informed on the SUPPLIER's own ongoing concomitant studies.

3. Although the SUPPLIER recognizes that the interchange of information is generally desirable in the field of treatment for AIDS, it is mutually understood that the SUPPLIER, in voluntarily supplying appropriately marked information deemed proprietary, including product and information regarding this product hereunder, is entitled to protection for any such technical information it may furnish.

   a. It is understood and agreed to, subject to applicable law, that the SUPPLIER shall retain all rights to those compounds or products in which the SUPPLIER has a proprietary interest. The SUPPLIER understands that contractors have the right to elect to retain title to inventions made under NIAID-supported contracts [37 CFR 401.14(b)]. The SUPPLIER deserves the right to reach an agreement with these contractors concerning the disposition of these intellectual property rights. The DIVISION agrees to notify the SUPPLIER of the names of the contractors prior to submitting compounds or products to them. Subject notwithstanding, to the provision that, with respect only to those drugs which have been determined by means of the various screening and testing processes to possess such significant activity (strong potential to be scheduled for clinical trial by the DIVISION, using mutually approved protocols), the Government shall have a royalty-free, irrevocable, nonexclusive license for clinical trials under any patent which the SUPPLIER may have or obtain on such compound or product or on a process for use of such compound or product, to manufacture and/or use by or for the Government the invention(s) claimed by the patent(s) only for medical research purposes related to or connected with the treatment of AIDS and associated infections including tuberculosis.

   b. The DIVISION agrees that the publication of biological data on products provided by the SUPPLIER is worthwhile and shall be encouraged. Specifically:

      (1) With regard to screening results on compounds in which the SUPPLIER has a proprietary interest, and that the DIVISION deems significant for the research on therapies for AIDS and associated infections including tuberculosis, the SUPPLIER agrees that the DIVISION may publish or otherwise publicly disclose such results after a period of 6 months from the date of final reporting of screening and testing results to the SUPPLIER in order for patent applications to be filed. The DIVISION will consult with the SUPPLIER prior to publication within this period on screening and testing results.

      (2) For all other compounds, the SUPPLIER will consult with the DIVISION prior to publishing screening data along with the available biological and physical data; such consent shall not be unreasonably withheld.

      (3) In no case will the DIVISION publish information identifying the SUPPLIER as the source of the compound without written approval.

   c. As soon as tests are completed and reported to the DIVISION, the SUPPLIER will receive from the DIVISION a full report including all screening data. The products scheduled for

clinical trial, referred to herein, shall be designated by the DIVISION, and the aforementioned report will specify the compounds so selected. The DIVISION shall be consulted whenever the SUPPLIER desires to include screening data in a publication, and appropriate credit shall be given to the U.S. Public Health Service.

The DIVISION is confident that this agreement will lay the basis for mutually satisfactory cooperation in the field and in the treatment of AIDS and associated diseases.

In agreeing to the above, the SUPPLIER signs below, as well as the attached duplicate of this agreement, and returns both to the DIVISION for countersignature. One original will be returned for the SUPPLIER's files.

Director, Division of AIDS NIAID, NIH	Name (Signature)
Date	Title
	Organization
	Address
	Date